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09/750,590	12/28/2000	Ira Herman	TUI-001CP	6511

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EXAMINER

PAPPU, SITA S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/31/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/750,590

Applicant(s)

HERMAN ET AL.

Examiner

Sita pappu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 13-19 and 23-28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 2 is/are allowed.
- 6) ☒ Claim(s) 3-12 and 20-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1-28 are pending in the instant application. This Office Action is in response to the communication filed by the Applicant in paper #13 on 02/25/02.

***Election/Restrictions***

Applicants' election, without traverse, of Group I, claims 1-12, 20-22 is acknowledged. Accordingly, claims 13-19, 23-28 are withdrawn from consideration as being directed to non-elected invention.

***Priority***

Applicants' claim of priority to the provisional application 60/170,182 filed 12/10/1999 is acknowledged.

***Drawings***

Draftsperson objected to the drawings. See attached PTO-948. Applicant is required to submit the drawing corrections within the time period set in this Office Action. See 37 C.F.R. 1.85(a). Failure to take corrective action within the set time period will result in ABANDONMENT OF THE APPLICATION.

***In the specification***

The disclosure is objected to because of the following informalities: The specification makes references to ATCC accession number throughout the disclosure (for example on page 2), but fails to provide the accession number of the deposit.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because it refers to a biological deposit to satisfy the "how to make" requirement, but fails to specify if it was made under the terms of the Budapest Treaty. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific cell line or cells have been deposited under the Budapest Treaty and that the cell line or cells will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

The specification, on page 12, discloses that a deposit will be maintained under the terms of the Budapest treaty, but does not disclose the deposit number. Thus, it is not clear if the Applicants intend to make a deposit, and intend to maintain it under the terms of the treaty, or whether a deposit has already been made.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,
- (d) a test of the viability of the biological material was performed at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

Claims 4-12, 20-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19UGPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed" Vas-Cath Inc. v. Mahurkar 19UGPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath Inc. v. Mahurkar 19UGPQ2d at 1116.

While the specification provides adequate written description for the claimed invention (methods and products) only with regard to the SeqID NO;1 and/or SEQ ID

NO:3 and the polypeptide encoded comprising the amino acid sequence set forth in SEQ ID NO:2 of beta CAP73, the specification fails to describe the other species within the genus of "nucleic acids that encode naturally occurring allelic variants of a polypeptide" or "nucleic acid molecules at least 60% identical to the nucleotide sequences of SEQ ID NO:1 or 3, or a fragment thereof". Further, the specification fails to describe the other species within the genus of "nucleic acid molecules encoding a polypeptide comprising an amino acid sequence at least about 50% identical to the amino acid sequence of SEQ ID NO:2". The specification fails to describe a representative number of the sequences encompassed by the said genus by their complete structure and other identifying characteristics, with particularity to indicate that applicants had possession of the claimed invention. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.* 45 USPQ2d 1641, 1646 (1995). In the instant case, the claimed embodiments of regulatory sequences other than those of SEQ ID NO:1 or 3 encoding a polypeptide of SEQ ID NO:2, lack a written description. The specification fails to describe what elements other than those isolated from bovine sequence, fall into this genus. The skilled artisan cannot envision the detailed chemical structure of the encompassed sequences isolated from any and all species, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the

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method. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. However, in the instant case, two specific nucleotide sequence species (SEQ ID NO:1 or 3, the latter being a fragment of SEQ ID NO:1) and one polypeptide species (SEQ ID NO:2) are described. However the claims encompass all sequences at least 60% identical to SEQ ID NO:1 or 3 and/or at least about 50% identical to SEQ ID NO:2. Thus, the specification must describe a representative number of the encompassed species by their complete structure. Next then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. In this case, since structure and/or function cannot be predicted from all the encompassed species of sequences, no identifying characteristics are provided for the claimed genus of sequences. This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of all the sequences that are encompassed by the claims, at the time the application was filed. With respect to claims 20-22, they depend from claims 4 and 5, thus, an essential element of the method and kit lacks written description.

Thus, it is concluded that the written description requirement is not satisfied for the claimed compositions and method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3, 6-12, 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite in its recitation of "deposited with ATCC as accession number\_\_\_\_\_". Applicant is advised to provide the accession number of the deposit.

Claims 6-12, 20-22 are rejected insofar as they depend from claim 3.

Claim 22 is indefinite in its recitation of "compound which selectively hybridizes to a nucleic acid". One of skill in the art would recognize that anything that "hybridizes" to a nucleic acid must be a nucleic acid. Other compounds that are not nucleic acids would not "hybridize" to a nucleic acid. Thus, the claim language is confusing in its use of the broad term compound".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



Claims 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilkin et al. (1996, J. Biol. Chem. Vol.271, No. 45, pp. 28451-28457).

Wilkin et al. teach a nucleotide sequence (GenBank accession number X99145, page 28454, right column, paragraph entitled "characterization of clones 5 and 3", last sentence) that is about 83% homologous to nucleotides 9 to 4730 of SEQ ID NO:1. Nucleotides 392-4597 of SEQ ID NO:1 encompass SEQ ID NO:3, and thus, the sequence of Wilkin et al. anticipates the sequence of claim 5.

Wilkin et al. further teach the cloning of their sequence in  $\lambda$ ZapII vector (page 28452, left column, paragraph 2), and generation of stocks in XL-1 blue E. coli. Wilkin et al. Also teach the expression of their sequence in dog thyrocytes cells (Fig. 3, page 28454).

Further, the sequence of Wilkin et al. is about 83% homologous to nucleotides 9 to 4730 of SEQ ID NO: 1 and can hybridize to nucleic acid molecules of any one of claims 1-5.

Thus, Wilkin et al. (1996) anticipate the invention of claims 5-11.

Claims 5-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al. (1998, PCT International Publication, WO 98/49302).

Jacobs et al. teach a nucleic acid encoding a polypeptide that is at least 50% identical to SEQ ID NO:2 (as claimed in claim 5, part 'c'). See claim 15, page 90; and SEQ ID NO:5, pages 64-66.

Jacobs et al. also teach the transformation of host cells and methods for producing the proteins of their invention by growing the cell culture (page 15, lines 17-29).

Thus, Jacobs et al. anticipated the invention of claims 5-12.

Claims 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Linskens et al. (1998, U.S. Patent No. 5,744,300).

Linskens et al. teach a sequence (SEQ ID NO: 38) that encodes a fragment of a polypeptide comprising at least 15 contiguous amino acid residues of the amino acid sequence of SEQ ID NO: 2. Nucleotides 3 through 59 of SEQ ID NO: 38 of U.S. patent 5,744,300 encode a fragment of a polypeptide that has contiguous homology over a length of 19 amino acid residues (residues 477-495) of SEQ ID NO: 2 of the instant invention. Linskens et al. further teach vectors and host cells (example 7, columns 25-28).

Thus, Linskens et al. anticipated the invention of claims 5-11.

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Wilkin et al. (1996, J. Biol. Chem. Vol. 271, No. 45, pp. 28451-28457).

The applicant claims an article of manufacture comprising a compound which selectively hybridizes to a nucleic acid molecule of any one of claims 1, 2, 3, 4, or 5 and instructions for use. Instructions as to the use of a product are not given patentable weight in a product claim where the body of the claim does not depend on the preamble

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for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that, "... in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." In re Casey, 152 USPQ 235 (CCPA 1967); In re Otto, 136 USPQ 458, 459 (CCPA 1963) (MPEP 2111.02). Wilkin et al. teach a nucleotide sequence (GenBank accession number X99145, page 28454, right column, paragraph entitled "characterization of clones 5 and 3", last sentence) that is about 83% homologous to nucleotides 9 to 4730 of SEQ ID NO: 1 and can hybridize to nucleic acid molecules of any one of claims 1-5.

Thus, by teaching all of the limitations of claim 22, Wilkin et al. clearly anticipates the instant invention.

Claims 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilkin et al. (1996, J. Biol. Chem. Vol. 271, No. 45, pp. 28451-28457).

Wilkin et al. teach a nucleotide sequence (GenBank accession number X99145, page 28454, right column, paragraph entitled "characterization of clones 5 and 3", last sentence) that is about 83% homologous to nucleotides 9 to 4730 of SEQ ID NO: 1 and can hybridize to nucleic acid molecules of any one of claims 1-5.

Wilkin et al. teach a method for detecting the presence of a nucleic acid molecule wherein the nucleic acid molecule comprises mRNA molecules by hybridizing the nucleic acid molecule with a cDNA probe (page 28452, right column, paragraph 1; Figures 1 and 2, page 28453).

Thus, by teaching all the limitations, Wilkin et al. anticipated the invention of claims 20 and 21.

**Conclusion**

Claims 1 and 2 are allowable.

Claims 3-12, 20-22 are not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305 1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308 4242 for regular communications and (703) 872 9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

S. Pappu  
July 26, 2002

*Anne-Marie Baker*  
ANNE-MARIE BAKER  
PATENT EXAMINER